In the Senate of the United States,

December 7, 2020.

Resolved, That the bill from the House of Representatives (H.R. 1503) entitled ''An Act to amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.'', do pass with the following

AMENDMENT:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Orange Book Transparency Act of 2020''.

SEC. 2. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

"(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

"(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

"(ii) a full list of the articles used as components of such drug;

"(iii) a full statement of the composition of such drug;

"(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

"(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

"(vi) specimens of the labeling proposed to be used for such drug;

"(vii) any assessments required under section 505B; and

"(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed

by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

"(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

"(II) claims a method of using such drug for which approval is sought or has been granted in the application.

"(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.".

(b) SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—

(1) IN GENERAL.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) is amended—

(A) by inserting before the first sentence the following: "Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent

number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application.";

(B) in the first sentence following the sentences added by subparagraph (A), by striking "which claims the drug for which" and all that follows through "of the drug." and inserting "described in subsection (b)(1)(A)(viii).";

(C) in the second sentence following the sentences added by subparagraph (A), by inserting after "could not file patent information under subsection (b) because no patent" the following:

"of the type for which information is required to be submitted in subsection (b)(1)(A)(viii)"; and

(D) by adding at the end the following: "Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.".

(2) UPDATING LIST.—Clause (iii) of section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by striking "(b) or".

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

"(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under—

"(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);

"(II) clause (iv) or (v) of paragraph (5)(B);

"(III) clause (ii), (iii), or (iv) of paragraph (5)(F);

"(IV) section 505A;

"(V) section 505E;

"(VI) section 527(a); or

"(VII) subsection (u).".

(d) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) AMENDMENT.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

"(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section—

"(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accord-

ance with the decision issued by the Patent Trial and Appeal Board or a court;

"(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

"(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).".

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(e) REVIEW AND REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health

and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) solicit public comment regarding the types of patent information that should be included on, or removed from, the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) transmit to Congress a summary of such comments and actions the Food and Drug Administration is considering taking, if any, in response to public comment pursuant to paragraph (1) about the types of patent information that should be included or removed from such list.

(f) GAO REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States (referred to in this section as the "Comptroller General") shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)) that claim an active ingredient or formulation of a drug in combination

with a device that is used for delivery of such drug, including an analysis of such patents and their claims.

(2) CONTENT.—The Comptroller General shall include in the report under paragraph (1)—

(A) data on—

(i) the number of patents included in the list published under section 505(j)(7) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(7)) that claim the active ingredient or formulation of a drug in combination with a device that is used for delivery of the drug, and that together claim the finished dosage form of the drug; and

(ii) the number of claims with respect to each patent included in the list published under such section 505(j)(7) that claim a device that is used for the delivery of the drug, but do not claim such device in combination with an active ingredient or formulation of a drug;

(B) an analysis of the listing of patents described in subparagraph (A)(ii), including the timing of listing such patents in relation to patents described in subparagraph (A)(i), and the

effect listing the patents described in subparagraph (A)(ii) has on market entry of one or more drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act as compared to the effect of not listing the patents described in subparagraph (A)(ii); and

(C) recommendations about which kinds of patents relating to devices described in subparagraph (A)(i) should be submitted to the Secretary of Health and Human Services for inclusion on the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act and which patents should not be required to be so submitted in order to reduce barriers to approval and market entry.

(g) CONFORMING AMENDMENTS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (c)(3)(E), by striking "clause (A) of subsection (b)(1)" each place it appears and inserting "subsection (b)(1)(A)(i)"; and

(2) in subsection (j)(2)(A)(vi), by striking "clauses (B) through (F) of subsection (b)(1)" and in-

serting "clauses (ii) through (vi) of subsection (b)(1)(A)".

Attest:

Secretary.

116TH CONGRESS
2D SESSION

H.R. 1503

AMENDMENT